UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF TEXAS
Fort Worth Division

Outsourcing Facilities Association, *et al.*, Plaintiffs, v. U.S. Food and Drug Administration, *et al.*, Defendants, and Eli Lilly and Company, Intervenor-Defendant.	Case No. 4:24-cv-00953-P

INTERVENOR-DEFENDANT ELI LILLY AND COMPANY'S RESPONSE TO THIS COURT'S MARCH 20 ORDER REGARDING THE ADMINISTRATIVE RECORD

On March 20, 2025, this Court "ORDERED that the Parties shall submit, on or before 5:00 p.m. on Tuesday, March 25, 2025, any excerpts from the administrative record that they wish the Court to see prior to the entry of a judgment on the merits." ECF No. 109 at 2 (bold removed). In response to that Order, Intervenor-Defendant Eli Lilly and Company ("Lilly") hereby submits, for the Court's convenience, Volume III of the administrative record, FDA 000247-000579, which comprises all "Information Provided by Eli Lilly and Company." *See* ECF No. 76. The documents numbered FDA 000247-000358 were submitted by Lilly to FDA before FDA issued its initial decision removing tirzepatide from the FDA shortage list on October 2, 2024. The documents numbered FDA 000359-000579 comprise Lilly's submissions starting October 2, 2024, and ending December 17, 2024. Lilly directs the Court's attention in particular to the following excerpts.

First, at the following pages, the Court can find the stock reports that Lilly submitted bi-weekly from mid-October through mid-December:

- FDA 000474 – October 18, 2024 Stock Report of Single-Dose Pens
- FDA 000475 – November 4, 2024 Stock Report of Single-Dose Pens
- FDA 000448 – November 18, 2024 Stock Report of Single-Dose Pens
- FDA 000483 – December 4, 2024 Stock Report of Single-Dose Pens
- FDA 000575 – December 15, 2024 Stock Report of Single-Dose Pens

Second, at the following pages, the Court can find graphic and tabular submissions showing historic and projected supply and demand of Lilly's tirzepatide products:

- FDA 000411-000412 – October 18, 2024 Demand/Supply Graphs for Single-Dose Pens
- FDA 000434-000435 – November 4, 2024 Demand/Supply Graphs for Single-Dose Pens
- FDA 000445-000446 – November 18, 2024 Demand/Supply Graphs for Single-Dose Pens
- FDA 000449-000451 – November 18, 2024 Demand/Supply Graphs for Vials
- FDA 000480-000481 – December 4, 2024 Demand/Supply Graphs for Single-Dose Pens
- FDA 000482 – December 4, 2024 Cumulative Demand/Supply Table for Single-Dose Pens
- FDA 000484-000486 – December 4, 2024 Demand/Supply Graphs for Vials
- FDA 000572-000573 – December 15, 2024 Demand/Supply Graphs for Single-Dose Pens
- FDA 000574 – December 15, 2024 Cumulative Demand/Supply Table for Single-Dose Pens
- FDA 000576-000578 – December 15, 2024 Demand/Supply Graphs for Vials

Third, at the following pages, the Court can find correspondence from FDA to Lilly showing how FDA probed the sources and methodologies of Lilly's submissions, following up on numerous occasions to seek clarity and/or additional data, as well as asking for responses to claims made in submissions from Plaintiffs and others supporting them:

- FDA 000415-000417 – October 28, 2024 FDA email to Lilly, *Tirzepatide Data Inquiries*
- FDA 000438-000440 – November 15, 2024 FDA email to Lilly, *Tirzepatide Supply/Demand – Responses to Questions and Biweekly Update*
- FDA 000453-000456 – November 26, 2024 FDA email to Lilly, *Tirzepatide Supply/Demand Update*

Fourth, at the following pages, the Court can find lengthy and detailed responses from Lilly, which repeatedly provided additional and/or more granular data at FDA's request, as well as information directly responding to many of the points Plaintiffs have pressed here:

- FDA 000422-000432 – November 5, 20245 Lilly letter to FDA responding to October 28, 2024 inquiries
- FDA 000459-000477 – December 6, 2024 Lilly letter to FDA responding to November 26, 2024 inquiries
- FDA 000488-000492 – December 6, 2024 Lilly submission to FDA regarding wholesaler inventory

Finally, at the following pages, the Court can find information Lilly provided FDA regarding its plans to add manufacturing sites and lines to further increase production:

- FDA 000307-000313 – August 23, 2024 Lilly's ongoing and planned submissions to FDA for new manufacturing sites and lines
- FDA 000423-000424 – November 5, 2024 Lilly letter to FDA responding to October 28, 2024 inquiries (these pages specifically address Lilly's new manufacturing site and line submissions to FDA)

* * *

These additional excerpts underscore not only that Lilly was regularly providing FDA with detailed, quantitative submissions but also that FDA thoroughly engaged with those submissions. It asked pertinent questions to clarify particular aspects of them and sought additional or more granular data when needed to better understand the complete supply-and-demand picture. The excerpts also confirm that Lilly has plans for further increasing its manufacturing capacity in 2025 and beyond which will ensure that Lilly's supply of Mounjaro® and Zepbound® will continue to meet and exceed demand going forward.

Dated: March 25, 2025

Respectfully submitted,

/s/ Dee J. Kelly, Jr.

Dee J. Kelly, Jr.
State Bar No. 11217250
KELLY HART & HALLMAN, LLP
201 Main Street, Suite 2500
Fort Worth, TX 76102
Telephone: (817) 332-2500
Facsimile: (817) 878-9280
dee.kelly@kellyhart.com

Paul D. Clement (*pro hac vice*)
Erin E. Murphy (*pro hac vice*)
Matthew Rowen (*pro hac vice*)
CLEMENT & MURPHY, PLLC
706 Duke Street
Alexandria, VA 22314
Telephone: (202) 742-8900
paul.clement@clementmurphy.com
erin.murphy@clementmurphy.com
matthew.rowen@clementmurphy.com

James F. Hurst, P.C. (*pro hac vice*)
Diana M. Watral, P.C. (*pro hac vice*)
Ryan Moorman, P.C. (*pro hac vice*)
Jame R.P. Hileman (*pro hac vice*)
KIRKLAND & ELLIS LLP
333 West Wolf Point Plaza
Chicago, IL 60654
Telephone: (312) 862-2000
james.hurst@kirkland.com
diana.watral@kirkland.com
ryan.moorman@kirkland.com
james.hileman@kirkland.com

Jay P. Lefkowitz, P.C. (*pro hac vice*)
KIRKLAND & ELLIS LLP
601 Lexington Avenue
New York, NY 10022
Telephone: (212) 446-4800
lefkowitz@kirkland.com

Attorneys for Intervenor-Defendant
ELI LILLY AND COMPANY

CERTIFICATE OF SERVICE

I certify that on March 25, 2025, I served the foregoing document and Eli Lilly's administrative record excerpt [Volume III, FDA 000247-000579] electronically in accordance with the Federal Rules of Civil Procedure. Eli Lilly's administrative record excerpt was filed separately under seal pursuant to the Stipulated Protective Order, ECF No. 61.

/s/ Dee J. Kelly, Jr.
Dee J. Kelly, Jr.